Introduction to Toxicity and Risk Assessment for Project Chemists

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Role of Risk Assessment on Environmental Projects

- Used to determine whether site requires further study or remediation
- Used with regulatory values to determine cleanup levels
- Risk-based screening levels (aka PRGs, RBCs, RSLs)
  - ► Screen sites early in project lifecycle
  - ► Determine project quantitation limits

Risk-Based Values Function of Toxicity and Exposure

$$\text{Risk} = \frac{\text{Intake}}{\text{Toxicity}}$$

↑ Toxicity = ↓ Criteria

- Tiered approach used to identify toxicity values for site risk assessments
- Other values: EPA provisional values, ATSDR, States
- EPA Integrated Risk Information System (IRIS) is the “gold standard”

Integrated Risk Information System

- Values used for site risk assessment and also for regulatory determinations (MCLs)
- May derive cancer oral slope factors (SF) and inhalation unit risks (IUR) and /or oral reference dose (RfD) and reference concentration (RfC) for noncancer effects
- If insufficient information exists a value is not derived

Definitions: Cancer Assessment

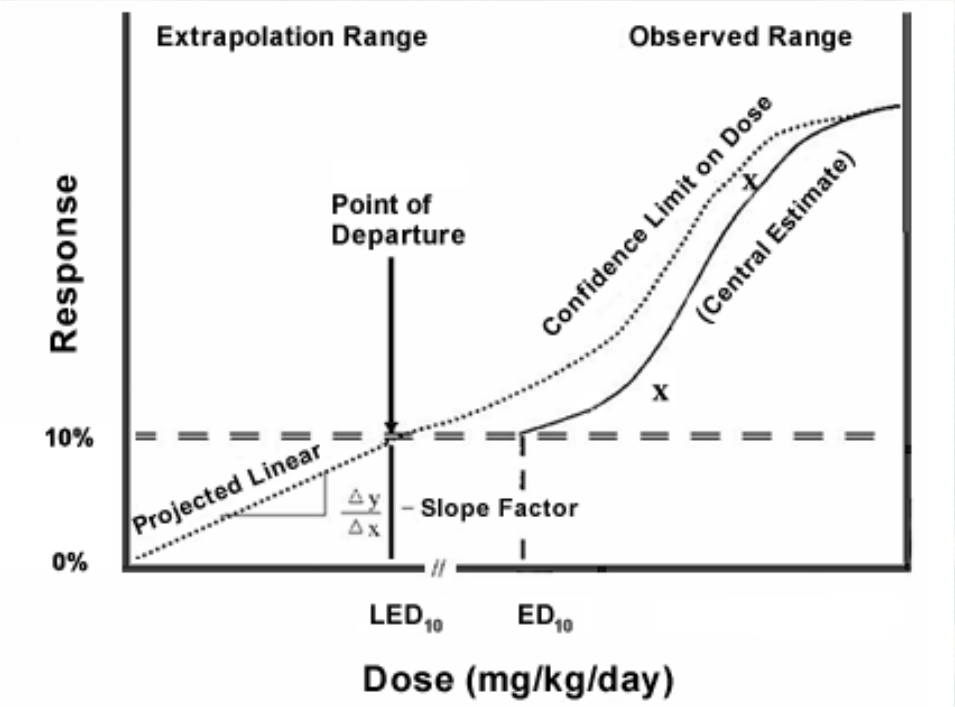
- Slope factor and Inhalation Unit Risk: A plausible upper-bound estimate of the probability of a response per unit intake of a chemical over a lifetime.
- OSF $(mg/kg\text{-}day)^{-1}$
- IUR $(\mu g/m^3)^{-1}$

Definitions: Non-Cancer

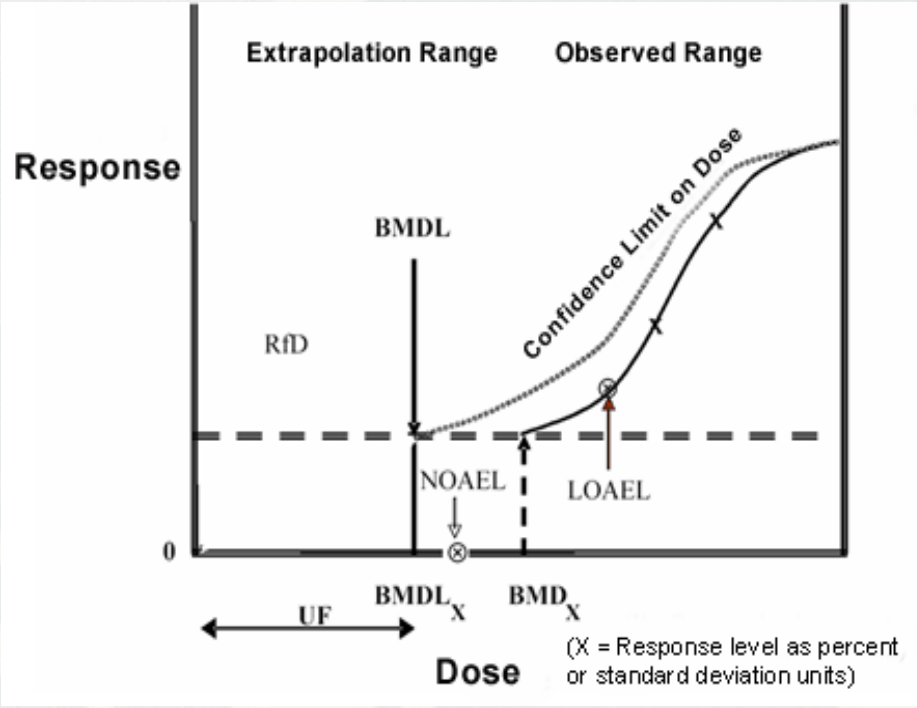
- Reference Dose (RfD) and Reference Concentration (RfC): An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure (or continuous inhalation exposure) to the human population that is likely to be without an appreciable risk of deleterious effects during a lifetime.

RfD mg-kg/day RfC mg/m^3

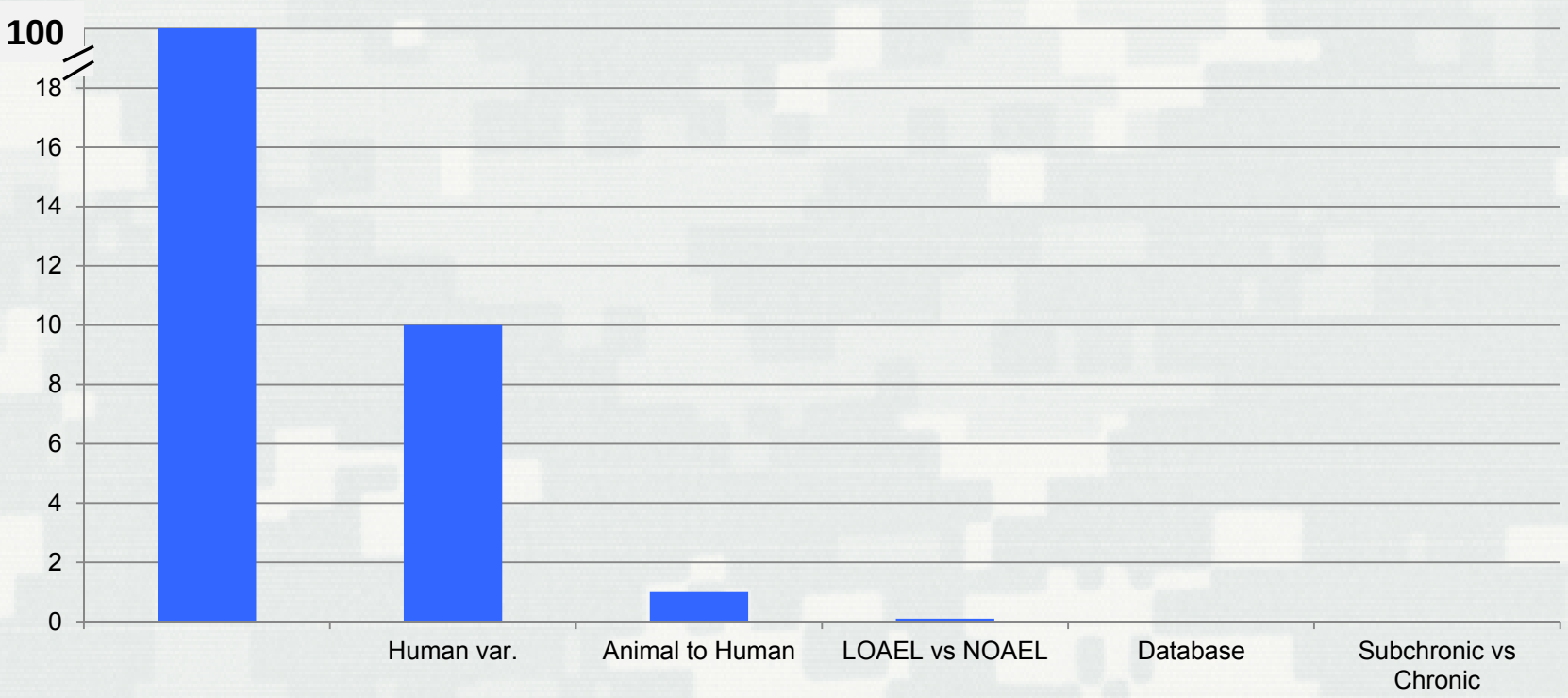
OSF Development



RfD Development



Uncertainty in Toxicity Values: Multiplicative Application of Uncertainty Factors



If total of UFs exceed 3000, by policy the RfD is not published. Here 100 mg/kg-day adjusted to 0.03 mg/kg-day.

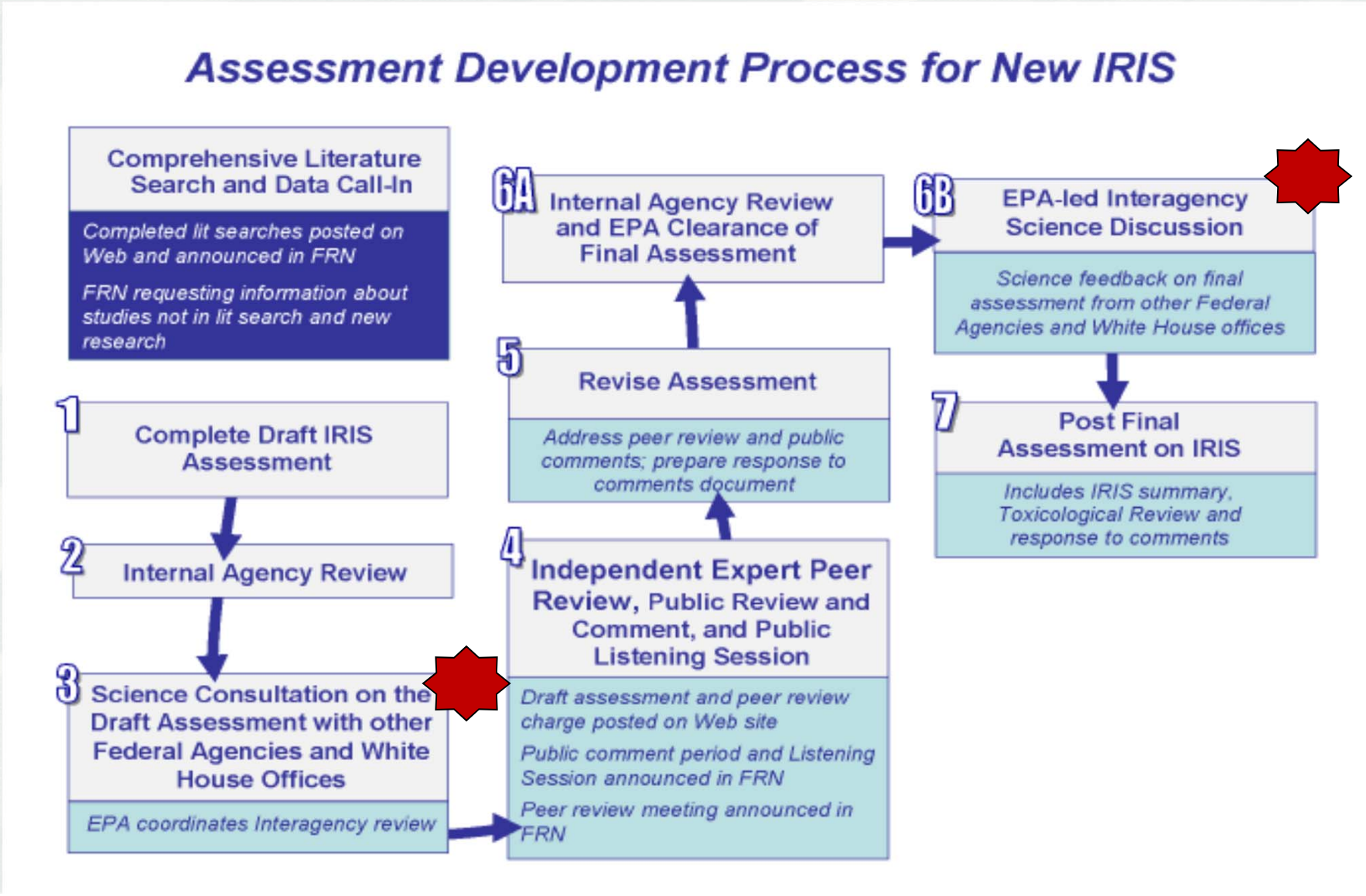
IRIS Process for Deriving toxicity Values

- Study identification
  - Literature search
  - Evaluate quality of studies
- Weight of Evidence
  - Mode of action – relevance to humans

IRIS Process for Deriving toxicity Values

- Dose – Response analysis
  - ▶ Model response in range of observation
    - Benchmark dose
  - ▶ Extrapolate to lower doses
    - Carcinogens
  - ▶ Consider sensitive populations and life stages
  - ▶ Apply uncertainty factors
    - Non-carcinogens

IRIS Assessment Development Process



Use of IRIS (and other) Toxicity Values

- Estimate risk associated with exposure to chemicals in environmental media at sites
- Used with estimates of exposure frequency and duration

Example: 5×10^{-5} excess cancer risk i.e. in addition to existing 1 in 2 or 3 cancer risk*

Hazard Quotient of 2

* American Cancer Society *Cancer Facts & Figures 2011*

Use of IRIS (and other) Toxicity Values

- Use with default exposure information to develop risk-based screening levels
- EPA harmonized regional PRGs and RBCs to the Regional Screening Levels
- **Screening levels are not cleanup levels!**

$$SL_{res\text{-}sol\text{-}nc\text{-}ing}\,(mg/kg) = \frac{THQ \times AT_r\left(\frac{365\ days}{year} \times ED_c\ (6\ years)\right) \times BW_c\ (15\ Kg)}{EF_r\left(\frac{350\ days}{year}\right) \times ED_c\ (6\ year) \times \frac{1}{RfD_o\left(\frac{mg}{Kg\text{-}day}\right)} \times IRS_c\left(\frac{200\ mg}{day}\right) \times \frac{10^{-6} Kg}{1\ mg}}$$

Why Aren't Screening Levels Cleanup Levels?

- Conservative by design
  - Default exposure values – not site specific
  - Non-carcinogen RSLs use childhood exposure of 6 years: More dose per unit body weight
  - All exposure pathways assumed to be complete
  - Some RSLs utilize toxicity values that are only suitable for screening

Unsure of site-specific exposure scenarios and factors.

Why Aren't Screening Levels Cleanup Levels or Limits?

- RSLs use $1x10^{-6}$ as the target risk; the acceptable risk range in the National Contingency Plan (NCP) is $1x10^{-4}$ - $1x10^{-6}$
- Site-specific PRGs derived at conclusion of the risk assessment and/or in the FS
- If an actionable risk is found i.e. > $1x10^{-4}$, analytical constraints are one factor provided by the NCP to adjust upward from $1x10^{-6}$

IRIS Assessment of Oral Toxicity of Hexavalent Chromium

- External review complete
- EPA will wait until studies underway on carcinogenic mode of action are complete to finalize the assessment
- NJ and Cal values for hex chrome

Risk-Based Screening Levels		
	Resident Soil (mg/kg)	Resident Water Use (µg/L)
DRAFT		0.04
Final (Aug'10)	4.85	0.67
RSL Table (NJ OSF)	0.29	0.031

Trichloroethylene Status: Final

- Lowest RSLs based on 10^{-6} cancer risk
- 1.6 E-04 mg/kg groundwater leachability

Risk-Based Screening Levels			
	Res. Soil (mg/kg)	Res. Water Use (µg/L)	Indoor Air (µg/m^3)
Old	2.8	2	1.2
Current	0.91	0.44	0.43

*Using EPA Regional Screening Level Calculator

EPA's Reanalysis of Key Issues Related to Dioxin Toxicity and Response to NAS Comments

- Oral noncancer reference dose (RfD) finalized Feb. 2012; cancer values will follow
- Draft cancer slope factor uses NIOSH occupational cohort data

Risk-Based Screening Levels		
	Residential Soil Noncancer Effects	Residential Soil Cancer Effects (DRAFT)
	50 ppt	0.45 ppt
1998 OSWER Value	1000 ppt	

Inhalation Assessment
1,4- Dioxane (Ext Review Draft)

- Oral SF and RfD finalized in 2010
- Noncancer reference concentration and inhalation unit risk

Risk-Based Screening Levels*			
	Resident Soil (mg/kg)	Resident Water Use (µg/L)	Air (µg/m^3)
Final (Aug'10)	4.85	0.67	
Draft			0.49

*Using EPA Regional Screening Level Calculator, basis 10^{-6} risk goal; Current air RSL is 0.32 µg/m^3 using CalEPA tox values

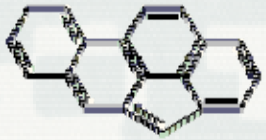
Carcinogenic PAHs and Relative Potency Factors

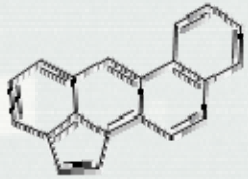
	Current RPF	Draft RPF	Δ
Benzo(a)pyrene	1	1	RSL 15µg/kg
Benz(a)anthracene	0.1	0.2	2x
Benzo(b)fluoranthene	0.1	0.8	8x
Benzo(k)Fluoranthene	0.01	0.03	3x
Chrysene	0.001	0.1	100x
Dibenz(a,h)anthracene	1	10	10x
Indeno(1,2,3-c,d)pyrene	0.1	0.07	

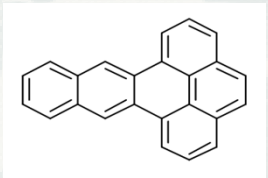
Additional PAHs from 2010 RPF Assessment

- Anthanthrene
- Benzo[g,h,i]perylene
- Benzo[j]fluoranthene
- Cyclopenta[c,d]pyrene
- Dibenzo[a,e]fluoranthene
- Dibenzo[a,e]pyrene
- Dibenzo[a,h]pyrene
- Dibenzo[a,i]pyrene
- Dibenzo[a,l]pyrene
- Fluoranthene

- Benz[b,c]aceanthrylene
- Benz[e]aceanthrylene
- Benz[j]aceanthrylene **(60x)**
- Benz[l]aceanthrylene
- Cyclopenta[d,e,f]chrysene
- Naphtho[2,3-e]pyrene







Vanadium Pentoxide Valence State May Matter…..

- IRIS reassessment undergoing external peer review
- Includes (new) cancer IUR which to some degree is dependent on solubility
- Current RSL table adjusts IRIS V_2O_5 RfD for V compounds (RSL = 400 mg/kg)
- Use of IUR in similar way would lead to vanadium in soil RSL below natural occurring levels of 7 to 500 ppm